



**510(k) SUMMARY OF
SAFETY AND EFFECTIVENESS INFORMATION**

A. Submitter Information:

Submitter's Name: ConMed Endoscopic Technologies, Inc.

Submitter's Address: 129 Concord Road,
Billerica MA 01821-7031

Contact Person: Thomas Hirte

Contact Person's Telephone Number: (978) 964-4252

Contact Person's FAX Number: (978) 964-4250

B. Device Name:

FXWire™ Advanced Measurement Guidewire

C. Predicate Devices:

XWire™ Next Generation Guidewire (K011759)

D. Device Description:

The FXWire™ Advanced Measurement Guidewire is a kink resistant metal alloy cored guidewire, which is encapsulated in a PTFE jacket. The guidewire has a flexible radiopaque tip, with a hydrophilic coating for enhanced lubricity. At the distal end of the guidewire, there are painted marker bands beginning at 6cm and extending to 30cm from the distal tip of the guidewire, as well as two radiopaque marker bands placed at 10cm and 15 cm from the distal tip of the guidewire. Additionally, at the proximal end of the guidewire, endoscopic marker bands have been placed beginning at 210cm and extending to 270cm from the distal tip of the guidewire. These marker bands enable endoscopic and fluoroscopic visualization of movement, as well as estimation of stricture length. This guidewire meets the recognized standard for high frequency current leakage (Reference ANSI/AAMI

Standard HF 18-1993) when used with a sphinctertome and may be left in place during electrosurgical cutting.

E. Intended Use:

The FXWire Advanced Measurement Guidewire is designed to be used to guide and exchange endoscopic accessories and electrosurgical devices for biliary procedures.

F. Technological Characteristics Summary:

The FXWire™ Advanced Measurement Guidewire device is a kink resistant metal alloy cored guidewire, which is encapsulated in a PTFE jacket. The guidewire has a flexible radiopaque tip, with a hydrophilic coating. At the distal end of the guidewire, there are painted marker bands beginning at 6cm and extending to 30cm from the distal tip of the guidewire, as well as two radiopaque marker bands placed at 10cm and 15 cm from the distal tip of the guidewire. Additionally, at the proximal end of the guidewire, endoscopic marker bands have been placed beginning at 210cm and extending to 270cm from the distal tip of the guidewire.

G. Performance Data:

Design verification data demonstrated that the FXWire™ Advanced Measurement Guidewire meets the same performance requirements and is as safe and effective as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 8 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Thomas Hirte, P.E.
Senior Regulatory Affairs Specialist
ConMed® Corporation
ConMed® Endoscopic Technologies, Inc.
129 Concord Road, Building 3
BILLERICA MA 01821

Re: K050304
Trade/Device Name: FXWire™ Advanced Measurement Guidewire
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 KOG
Dated: February 3, 2005
Received: February 8, 2005

Dear Mr. Hirte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

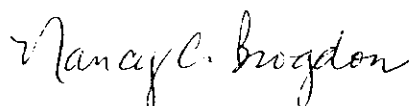
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): TBD K050304

Device Name: FXWire™ Advanced Measurement Guidewire

Indications For Use: To be used to guide and exchange endoscopic accessories and electrosurgical devices for biliary procedures. The guidewire is indicated for selective cannulation of the biliary ducts, including but not limited to the common bile, cystic, pancreatic, and right and left hepatic ducts.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David H. Johnson
(Division Sign-Off)
Division of Research
and Radiological Devices
510(k) Number K050304